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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,335	01/15/2004	Seth J. Orlow	71369.368 and PFI-016CIPD	6410

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EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,335	ORLOW ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, 32-36 and 38-43, drawn to a method of screening for compounds that inhibit melanogenesis comprising treating cells expressing a tyrosine-encoding gene with a test compound that inhibits melanogenesis, classified in class 435, subclass 7.23. Claims 32-36 and 38-43 will be examined with this Group to the extent the method reads on inhibiting P protein.

II. Claims 18-34 and 37-43, drawn to a method of screening for compounds that increase melanogenesis comprising treating cells expressing a tyrosine-encoding gene with a test compound that increases melanogenesis, classified in class 435, subclass 7.23. Claims 32-34 and 37-43 will be examined with this Group to the extent the method reads on increasing P protein.

III. Claims 44-56, drawn to methods of decreasing melanin production in a melanocyte comprising contacting the melanocyte with an effective amount of a compound that effects an alteration in late endosomal/lysosomal trafficking, classified in class 435, subclass 7.1+ and Claims 57-69, drawn to a method of reducing skin pigmentation comprising contacting skin with a pharmaceutically effective amount of a

compound that effects an alteration in endosomal/lysosomal trafficking, classified in class 424, subclass 9.1+..

IV. Claims 70-73, drawn to a method of activating melanogenesis comprising contacting a melanocyte with diminished or absent P protein activity with a compound that inhibits ATPase, classified in class 435, subclass 7.1+.

V. Claims 74-77, drawn to a method of treating tyrosinase-positive, oculocutaneous albinism in an individual in need thereof comprising contacting the skin of the individual with a pharmaceutically effective amount of a compound that inhibits ATPase, classified in class 424, subclass 78.02.

The inventions are patentably distinct and/or independent, each from the other because of the following reasons:

2. The inventions of Group I and II are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case the different inventions of Groups I and II have opposite biological effects, specifically Group I is directed to screening for compounds that inhibit melanogenesis whereas Group II is directed to screening for compounds that increase melanogenesis. Compounds that act to inhibit melanogenesis would not be the same compounds that act to increase melanogenesis.

Compounds that have opposite biological effects are mutually exclusive (i.e. one compound cannot have both a positive and negative effect on melanogenesis). Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. While Groups I and II can be identically classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner because a search for inhibitors of melanogenesis would not lead to the same results as a search for compounds or methods that lead to an increase in melanogenesis. Thus, Groups I and II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

3. The method claims of Groups I-II and III are patentably distinct and/or independent for the following reasons. The method claims of Group III are drawn to decreasing melanin production in a melanocyte comprising contacting the melanocyte with an effective amount of a compound that effects an alteration in late endosomal/lysosomal trafficking whereas the method claims of Groups I and II are directed to screening for compounds that affect cellular tyrosinase localization, tyrosinase protein levels, and tyrosinase activity. In addition, the specific assays and the endpoints of those assays are not the same for each invention. As such, the compounds identified in the methods of Groups I and II as having positive or negative effects on melanogenesis will not necessarily be the same compounds that affect late endosomal/lysosomal trafficking in the method of Group III and vice versa. Therefore,

Groups I-II and III are distinct. The search burden is as least as burdensome as noted between Groups I and II. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. The methods of Groups I-II and the methods of Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method claims of Groups I-II do not overlap the scope of the method claims of Group IV and vice versa as evidenced by the distinct functions of the claimed inventions. The method claims of Group IV are drawn to activating melanogenesis with a compound that inhibits ATPase whereas the method claims of Groups I and II are drawn to screening for compounds that affect tyrosinase localization, protein expression, and activity as explained above. Thus, the compounds identified in the method claims of Groups I and II as having an affect on tyrosinase localization, expression levels, and/or activity would not necessarily have an effect on ATPase. Therefore, Groups I-II and IV are distinct. Because these inventions are distinct for the reasons given above and the search required for Group I or Group II is not required for Group IV, restriction for examination purposes as indicated is proper. While Groups I-II and IV can be similarly classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner because a search for modulators of tyrosinase localization, expression, and/or activity would not lead to the same results as a search for compounds or

methods that lead to an increase in melanogenesis due to inhibition of ATPase. Thus, Groups I-II and IV have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

5. Groups I-II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method claims of Groups I-II are carried out in vitro and are drawn to methods of screening for compounds that affect tyrosinase localization, protein expression, and activity as explained above, whereas the method claim of Group V is carried out in vivo and is drawn to a method of treating tyrosinase-positive, oculocutaneous albinism in an individual in need thereof comprising contacting the skin of the individual with a pharmaceutically effective amount of a compound that inhibits ATPase. The different inventions of method Groups I-II and V comprise different method steps, which yield different results and endpoints. Therefore, Groups I-II and V are distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. The inventions of Group III and IV-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method claims of Group III do not overlap the

scope of the method claims of Groups IV and V and vice versa as evidenced by the distinct functions of the claimed inventions. The methods of Groups IV and V are drawn to activating melanogenesis with a compound that inhibits ATPase whereas the method claims of Group III are drawn to methods of decreasing melanin production both in vitro and in vivo with an effective amount of a compound that effects an alteration in late endosomal/lysosomal trafficking. Thus, a compound used in the method claims of Groups IV and V that inhibits ATPase and activates melanogenesis (i.e. increased melanin production) could not have the effect of decreasing melanin production as in the method claims of Group III. Therefore, Group III and IV-V are distinct. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group IV or V, restriction for examination purposes as indicated is proper. While Groups III and IV can be similarly classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner because a search for decreased melanin production would not lead to the same results as a search for compounds or methods that lead to an increase in melanogenesis due to inhibition of ATPase. Thus, Group III and IV-V have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

7. The inventions of Group IV and V are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have materially different design, mode of operation,

function, or effect. See MPEP 806.05(j). In the instant case, although the method claims of Groups IV and V both relate to the use of compounds that activate melanogenesis through inhibition of ATPase, the method claims of Group IV do not overlap the scope of the method claims of Group V and vice versa as the method of Group IV is not disclosed as being used in the method of Group V and the different inventions have different endpoints and use different systems (e.g. the method of Group IV is directed to an in vitro assay, whereas the method claim of Group V is directed to treatment of tyrosinase-positive, oculocutaneous albinism in vivo). Therefore, Groups IV and V are distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election

8. A telephone call was made to Dr. Ann-Louise Kerner on March 29, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James D. Anderson JDA
Examiner
Art Unit 1614

JDA

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